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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,851	11/03/2003	Yoh-ichi Matsumoto	019026 00011OUS	3540

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,851	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Preliminary Amendments*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☒ Claim(s) *7,11-17,20 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/02,6/04,11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Preliminary Amendments, received 17 November 2000, 18 December 2001, and 23 July 2002, are acknowledged.

2. Claims 1-33 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 1, lines 9-11, statement that the application is a 371 should be included in the priority statement.

Page 4, line 18, "competes" should be "compete"; line 30, "binds" should be "bind".

Page 7, line 13, "lines" should be "line"; line 16, "producing" should be "Producing" to be consistent with the rest of the specification.

Page 8, line 10, "producing" should be "Producing" to be consistent with the rest of the specification; line 33, "verotoxin" should be "Verotoxin" to be consistent with the rest of the specification.

Page 9, line 7, "Recognized" should be "recognized".

Page 12, line 25, "producing" should be "Producing" to be consistent with the rest of the specification.

Page 14, line 2, delete the period immediately following "reference".

Page 17, line 30, The American Type Culture Collection address cited in the specification is no longer correct. Effective 23March1998, the correct address is 10801 University Boulevard, Manassas, VA 20110-2209.

Page 18, line 11, the parenthesis immediately following the period should be deleted.

Page 21, line 3, "Verotoxinproducing" should be "Verotoxin Producing" to be consistent with the rest of the specification; line 16, delete the ' immediately prior to human.

Page 22, line 22, "producing" should be "Producing" to be consistent with the rest of the specification.

Page 23, line 17, "producing" should be "Producing" to be consistent with the rest of the specification.

Appropriate correction is required.

Deposit Requirement

4. The specification teaches a monoclonal mouse antibody with the laboratory designation of VTm1.1, and a cell line that produces a humanized version of the antibody. The specification lacks complete deposit information for the deposit of either the mouse antibody VTm1.1 or a cell line which produces a humanized version of the antibody. Because it is not clear that any other antibodies possessing the properties of mouse antibody VTm1.1 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of mouse antibody VTm1.1 for the production of humanized antibody VTm1.1, a suitable deposit for patent purposes is required. Without a publicly available deposit of either the above mouse antibody VTm1.1 and/or the cell line that produces a humanized version of the antibody, one of skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the mouse antibody VTm1.1 is an unpredictable event. Note that the best mode is not satisfied by a written disclosure unless the exact embodiment is reasonably reproducible from that disclosure. If reproducibility of the mouse antibody VTm1.1 is not established, failure to deposit either the mouse antibody VTm1.1 and/or the cell line that produces a humanized

version of the antibody would result in concealment of the best mode contemplated by applicant for carrying out the invention. In re Sherwood, 615.2d 809, 204 USPQ 537 (CCPA 1980).

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each nation. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §§1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) the name and address of the depository,

2) the name and address of the depositor,

3) the date of deposit,

4) the identity of the deposit and the accession number given by the depository,

5) the date of the viability test,

6) the procedures used to obtain a sample if the test is not done by the depository, and

7) a statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the mouse antibody VTm1.1, and/or the cell line that produces a humanized version of the antibody, described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundeck, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §§1.801-1.809 for further information concerning deposit practice.

Claim Objections

5. Claims 7, 11-17, 20, and 33 are objected to because of the following informality: following amendment of the claims, the language of the claims which recite, "of any of claims 1" is stilted and should be reworded to recite "of claim 1". Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 6 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is directed to any antibody which binds to VT2 and/or VT2 variants without any recitation of purification or isolation or host source. Therefore, the claim reads on any antibody produced in a host infected with VTEC.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5-10, 12-13, 18-19, 21, 23, 28, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a laboratory designated mouse antibody, Vtm1-1. This is merely a laboratory designation and therefore indefinite without a deposit of the antibody (see *supra*).

10. Claims 5-10, 12-13, 18-19, 21, 23, 28, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if the antibody in the claim, designated as "VTm1-1" is identical to the antibody in the specification, designated as "VTm1.1".

11. Claims 5-13, 18-19, 21, 23, 28, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 11, 12, 13, 29 are drawn to sequences "as shown in Fig. X". This is indefinite because the figures may be amended at any time and would change the claimed invention. It is recommended that the claims recite the SEQ ID NO of the claimed sequences. Claims 6-10, 18-19, 21, 23, and 28 depend from the claims but do not clarify the indefiniteness.

12. Claims 1-4 and 6-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for humanized mouse antibodies which neutralize VT2, does not reasonably provide enablement for humanized mouse antibodies which bind specifically to VT2 and/or VT2 variant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention are a humanized antibody which neutralizes VT2 and methods of using said antibodies.

The amount of direction or guidance present in the instant specification is insufficient for the broad scope of the claims, i.e., a humanized antibody or any antibody which binds specifically to VT2 and/or VT2 variants. While the specification does teach one humanized mouse antibody which neutralizes VT2 and certain VT2 variants, the specification does not teach any specificity characteristics, i.e., that the antibody binds only to VT2 or the epitope(s) to which the antibody binds. Thus, the scope of the instant claims constitute merely an invitation to experiment without an expectation of success.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

June 24, 2006